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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,464	08/25/2003	James D. Ralph	F-286	8288

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SPINE MP  
LERNER, DAVID, et al.  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

EXAMINER
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BLANCO, JAVIER G

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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12/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/648,464

Applicant(s)

RALPH ET AL.

Examiner

Javier G. Blanco

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-16, 18, 20, 21 and 23-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-16, 18, 20, 21, and 23-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1<sup>st</sup>, 2007 has been entered.

### ***Response to Amendment***

2. Applicants' amendment of claims 13, 16, and 21 in the reply filed on November 1<sup>st</sup>, 2007 is acknowledged.

3. Applicants' addition of claims 27-35 in the reply filed on November 1<sup>st</sup>, 2007 is acknowledged.

### ***Claim Objections***

4. Claim 13 is objected to because of the following informality: please substitute "is spaced from and confronts the said inner surface" (see lines 16 and 17) with --is spaced from and confronts the said inner surface--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29, 32, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding each of claims 29, 32, and 35, the limitation “said spring has holes at opposite ends” is unclear. It is unclear how the “opposite ends” relate to the claimed “spring” or “socket” since none of independent claims 13, 16, and 21 provides structure for the “spring” or “socket”. Critical structure necessary for accomplishing the claimed function must be set forth. Said limitation will be broadly interpreted.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 13, 16, 18, 20, 21, 23, 27, 28, n30, 31, 33, and 34 are rejected under 35

U.S.C. 102(b) as being clearly anticipated by Berry (US 5,895,428; cited in Applicants' IDS).

As seen in Figures 2 and 4, Berry discloses an intervertebral spacer device comprising first (21) and second (35) plates, each having an external plate surface thereof, wherein an inner surface of said first plate comprises a ball-shaped structure (spherical section 29) extending

therefrom and an inner surface of the second plate has a socket (41+ 43) affixed thereto, said socket having an opening/curvate volume (see Figures 2 and 4). Said socket has a top side with a curved convex surface (41) that extends from the curvate volume and confronts said inner surface of said first plate (21), and an underside with a curved concave surface (43 and/or 45) that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate.

As seen in Figures 2 and 4, Berry discloses an intervertebral spacer device comprising first (35) and second (21) plates, each having an external plate surface thereof, wherein an inner surface of said first plate (35) comprises a ball-shaped structure (spherical nut 13, which is part of member 35 via attachment to screw 47) extending therefrom and an inner surface of the second plate (21) has a socket (see socket formed by spherical section 29) affixed thereto, said socket having an opening/curvate volume (see Figure 4). Said socket has a top side with a curved convex surface (convex surface of 29) that extends from the curvate volume and confronts said inner surface of said first plate (35), and an underside with a curved concave surface (concave surface of 29) that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate (21).

As seen in Figures 9 and 11, Berry discloses an intervertebral spacer device comprising first (plate 35 of fitting 101) and second (**first interpretation:** fitting 105; **second interpretation:** fitting 103; **third interpretation:** fitting 105 + fitting 103) plates, each having an external plate surface thereof, wherein an inner surface of said first plate (35) comprises a ball-shaped structure (spherical nut 13, which is part of member 35 via attachment to screw 47) extending therefrom and an inner surface of the second plate has a spring/socket (**first**

**interpretation:** fitting 109; **second interpretation:** fitting 109 + fitting 105) affixed thereto, said spring having an opening/curvate volume (see Figures 9 and 11). Said spring/socket has a top side with a curved convex surface (convex surface of fitting 109) that extends from the curvate volume and confronts said inner surface of said first plate (35), and an underside with a curved concave surface (concave surface of fitting 109; concave bottom surface of fitting 105) that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate. Berry disclose the implant as made from either metal and/or ceramic (see column 6), and the spring as able to counteract the load applied to at least one of the plate.

**Note:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 13, 16, 18, 20, 21, 23, 27, 29, 30, 32, 33, and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Xavier et al. (US 6,063,121 A).

As seen in Figures 1-5, Xavier et al. disclose an intervertebral spacer device (10) comprising first (20) and second (48) plate members, each having an external plate surface thereof, wherein an inner surface of one of said plate members comprises a ball-shaped structure (ball supporting member 42 + ball 46, or ball 46 by itself) extending therefrom and an inner

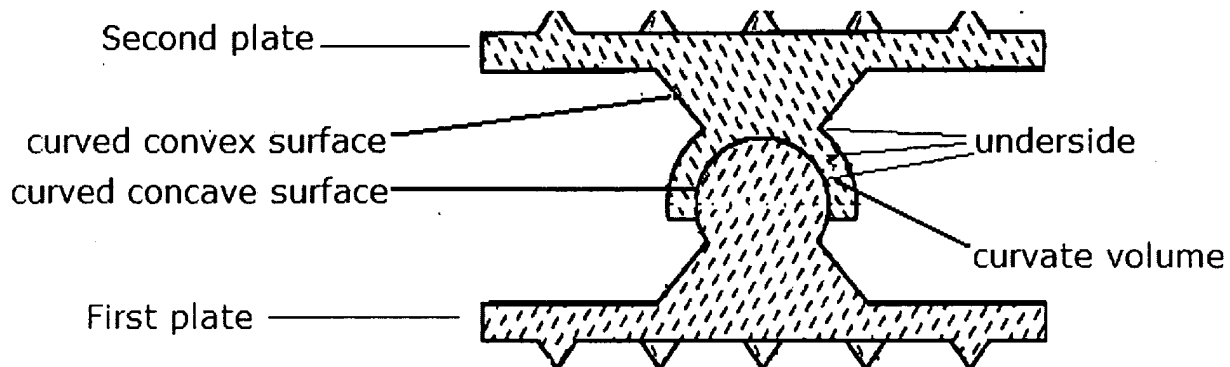
surface of the other one of said plate members has a spring (**first interpretation:** socket supporting member 62 and socket 68; **second interpretation:** cushion 80; **third interpretation:** socket supporting member 62 + socket 68 + cushion 80; **fourth interpretation:** socket 68 by itself) affixed thereto, said spring having an opening/curvate volume (**first interpretation:** socket 68; **second interpretation:** central aperture 90; **third interpretation:** socket 68 + central aperture 90). Xavier et al. disclose socket supporting member 62, socket 68, ball supporting member 42, and ball 46 as made from either metal or ceramic (see column 4, lines 50-64), and able to counteract the load applied to at least one of the plate members (see column 4, lines 11-20). The spring/socket having a top side with a curved convex surface that extends from the curvate volume and confronts (i.e., face) the one of said plates and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts (i.e., face) the other one of said plates. Regarding claims 29, 32, and 35, plates/extensions 34 comprises through holes with fasteners 38 extending through said holes that further contributes to secure the spring/socket to the second plate.

**Note:** Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Figure 5 of Xavier et al. '121 is shown below:



### *Response to Arguments*

10. With regards to Xavier et al. '121, Applicants' arguments filed November 1<sup>st</sup>, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Xavier et al. '121 do not disclose newly added limitation: *"said spring having a top side with a curved convex surface that extends from the curvate volume and confronts said inner surface of said first plate and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts said inner surface of said second plate"*. The Examiner respectfully disagrees. See representation of Figure 5 of Xavier et al. '121 above. The term "confronts" is generally defined as "to bring or come face to face". The "curved convex surface" of the "spring/socket" faces an inner surface of the first plate, and the "spring/socket" has a concavity ("curved concave surface") facing or confronting an inner surface of the second plate (either facing the planar, flat surface of the second plate, and/or facing the curved surface of the "spring/socket", which is part of the inner surface of the second plate).



11. Claims 13, 16, 18, 20, 21, 23, and 27-35 are rejected under 35 U.S.C. 102(e) as anticipated by Ralph et al. (US 5,989,291; previously cited in PTO-892) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ralph et al. (US 5,989,291; previously cited in PTO-892) in view of Bryan et al. (US 6,156,067; cited in Applicants' IDS).

As seen in Figures 3b, 4, 5, and 7-9, Ralph et al. disclose an intervertebral spacer device comprising first and second plate members (e.g., 100a, 100b), each having an external plate surface (e.g., 102a, 102b) thereof, the plate members being disposed such that the external plate surfaces face in opposite directions. Ralph et al. disclose plate members 100a, 100b as convex (see column 2, lines 61-63) and as having a porous coating (see column 3, lines 4-6; column 5, lines 57-61). Additionally, Ralph et al. teach a porous, resilient/flexible (i.e., deflectable; see column 3, lines 8-18; column 6, lines 17-21), and convex (see Figures 4 and 9) fabric/mesh (circumferential wall 120) on an external lateral portion of the intervertebral spacer device (see Figures 4, 6, and 9). The ball attached with one of the plates is ball-shaped head 207. The spring/socket affixed with the other one of said plates is spring 230. As seen in Figures 8 and 9, the spring/socket having a top side with a curved convex surface that extends from the curvate volume 232/233 and confronts (i.e., face) the one of said plates and an underside with a curved concave surface that extends from the curvate volume and is spaced from and confronts (i.e., face) the other one of said plates. Regarding claims 28, 31, and 34, Figure 9 clearly shows the spring as having at least one hole (as part of the curvate volume) extending therethrough and a fastener extending through the at least one hole.

a. The term "affixed" is commonly defined as "to secure to something"; "to fix one thing to another". The spring/socket 230 will be affixed once the prosthesis is assembled since the

assembly will prevents physical separation. Ralph et al. '291 disclose spring/socket 230 as "compressible retained in the interior of the device". Even if the second plate will shift from left to right, spring/socket 230 will be affixed and secured to the second plate.

b. Bryan et al. disclose (see Figures 6, 9, and 10) the subject matter of using threaded fasteners (e.g., screw 362; screw 92) in order to attach the ends of a spring (e.g., endoprosthetic vertebral body 320; ligament 250) to intervertebral plates (see plates 322, 324). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of using threaded fasteners, as taught by Bryan et al., with the spring of Ralph et al. '291, in order to attach said spring to intervertebral plates.

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

### ***Response to Arguments***

12. With regards to Ralph et al. '2911, Applicants' arguments filed November 1<sup>st</sup>, 2007 have been fully considered but they are not persuasive.

The Applicants argue that Ralph et al. '291 do not disclose the socket/spring as "affixed" to the inner surface of one plate. The Examiner respectfully disagrees. The term "affixed" is

commonly defined as “to secure to something”; “to fix one thing to another”. The spring/socket 230 will be affixed to the inner surface of one plate once the prosthesis is assembled since the assembly will prevent physical separation. Further, as the Applicants noted, Ralph et al. ‘291 disclose spring/socket 230 as “compressible retained in the interior of the device”. Even if the second plate will shift from left to right, spring/socket 230 will be affixed and secured to said second plate.

*Claim Rejections - 35 USC § 103*

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xavier et al. (US 6,063,121 A) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants’ IDS).

Xavier et al. disclose the invention as claimed (see 102(b) rejection above). Xavier et al. did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first (top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4;

see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Xavier et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

15. Claims 14, 15, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al. (US 5,989,291; previously cited in PTO-892) in view of Stubstad et al. (US 3,867,728 A; cited in Applicants' IDS).

Although Ralph et al. disclose the external plate surfaces as convex to match the contour of the opposing bone surface (see column 2, lines 61-65), and a porous coating on said external plate surfaces to provide for tissue ingrowth (see column 3, lines 4-6; column 5, lines 57-61), they did not particularly disclose said external plate surfaces as having a deflectable/deformable surface (or mesh) thereon. However, this is well known in the art. For example, Stubstad et al. disclose (see Figures 1, 2, and 4) an intervertebral spacer device (device 10) comprising: (i) first

(top element 11) and second (bottom element 12) plate members, each having an external plate surface, at least one of the external plate surfaces having a deflectable/movable (i.e., capable of being deflected/moved; see column 8, lines 46-49; column 9, lines 14-17), convex (see Figure 4; see column 13, lines 24-26), wire mesh (e.g., Dacron mesh 21 and/or Dacron mesh 20; see column 8, lines 6-10 and lines 43-59; column 9, lines 10-18). The device further comprises a force-restoring element (e.g. core 15) disposed between the first and second plate members (see entire document). Stubstad et al. teach said deflectable/deformable, convex wire mesh disposed on said external plate surfaces in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces (see columns 8 and 9). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an intervertebral spacer device comprising external plate surfaces having a deflectable/deformable, convex wire mesh thereon, as taught by Stubstad et al., with the intervertebral spacer device of Ralph et al., in order for the external plate surfaces to adapt/match to any small irregularities in the vertebral surfaces and to enable deeper tissue ingrowth on said external plate surfaces.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for

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the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 3, 2007

Javier G. Blanco

A large, stylized handwritten signature in black ink, consisting of a large loop followed by a series of overlapping strokes that form a complex, abstract shape.A handwritten signature in black ink, appearing to be 'David H. Willse', written in a cursive style with a long horizontal line extending from the end.

David H. Willse  
Primary Examiner